

***SUMMARY OF THE 1995 INTERIM MEETING OF THE
NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE***

***December 6-8, 1995
Arlington, Virginia***

Opening Plenary Session

The 1995 Interim Meeting of the National Environmental Laboratory Accreditation Conference (NELAC) was opened by Dr. Robert Stephens, NELAC Chair and also Chief of the State of California Hazardous Materials Laboratory. The meeting was attended by approximately 200 representatives from the US EPA, other Federal agencies/programs, state government agencies, county/ local government agencies, environmental testing laboratories, laboratory accreditation organizations, industry, academia, environmental interest groups, and other self-designated affiliations. Analysis of the attendees from state governments, which are a key to the NELAP process, revealed that 31 states were represented.

In an opening plenary session, Dr. Stephens reminded attendees that the purpose of NELAC and its associated National Environmental Laboratory Accreditation Program (NELAP) is to establish, in an open forum, uniform national accreditation standards for environmental laboratories. Dr. Stephens set as a goal for this working meeting to “come substantially close” to getting the NELAP draft standards ready for publication in the next two to three months.

NELAC Director Ramona Trovato, also Director of EPA’s Office of Radiation and Indoor Air, provided some background history of the events leading to the development of NELAP. After listing many of the commonly acknowledged problems with the current accreditation process for environmental laboratories, Ms. Trovato traced the roots of NELAP through the Environmental Monitoring Management Council (EMMC) Ad Hoc Panel, the Committee on National Accreditation of Environmental Laboratories (CNAEL), and the State/EPA Focus Group.

Dr. Charles Hartwig, NELAC Chair-Elect from the Florida Department of Health and Rehabilitative Services, then brought attendees up-to-date on the current status of NELAC. Topics covered included a review of the development and revision of the NELAC Constitution and By-Laws; the expansion of NELAC standing committees to allow greater private sector involvement; establishment of an Environmental Laboratory Advisory Board (ELAB); and formation of Ad Hoc committees to address GLP issues, field measurements, and coordination among the NELAC standing committees. He reminded everyone of the Technology Transfer Network (TTN) electronic bulletin board available to the regulating and regulated communities through the Office of Air Quality and Planning Standards (OAQPS). He concluded his presentation by announcing that Belinda Collins of the National Institute of Standards and Technology (NIST) serves as liaison between the Laboratory Accreditation Working Group (LAWG) and NELAC, and by reviewing several pieces of pending Federal legislation that may affect the NELAP process.

The Keynote Address for the opening session was given by Henry Longest, Deputy Assistant Administrator for EPA’s Office of Research and Development (ORD). Mr. Longest brought a message of strong support for NELAC within the Agency and ORD in particular. He recognized the accomplishments of NELAC to date and emphasized the significance of EPA’s establishing ELAB at a time when the Agency is under pressure to reduce the number of advisory boards. Mr. Longest expressed appreciation for the spirit of cooperation that pervades NELAC and for the value of the partnerships that have developed as a result. He concluded that these partnerships, and an embracing of the international

community, are keys to the future success of NELAP. He also noted that the NELAP concept fits well the mold of the “federal government of the future” in that it maximizes involvement of the states in order to better deliver government services that the public needs.

Ms. Jeanne Mourrain, NELAC Executive Secretary, reviewed the schedule and location of the upcoming committee work sessions that represent the major thrust of the Interim Meeting. She introduced the concept of “committee reports” which comprised the remainder of the opening session and reminded the audience that written comments on specific committee or broader NELAC issues were still being accepted and can be submitted through the TTN bulletin board. She closed by noting that the Second Annual NELAC will be held in the Washington area, perhaps in July.

The remainder of the morning session was devoted to updates from chairs of all seven standing committees and three of the four administrative committees of NELAC. Each chair described the nature and frequency of his or her committee’s work since the First Annual NELAC in February 1995, the accomplishments of the committee to date, and issues and concerns each hoped to address and/or resolve during the Interim Meeting. Chairs reported having made considerable efforts to address comments and concerns aired by attendees of the February meeting and to amend or modify the draft Standards and/or Constitution and By-Laws where possible to accommodate those comments. Many chairs noted that the work of their committees was not complete and that they were seeking input from all interested parties during the Interim Meeting.

The opening plenary session concluded with reports from ELAB and a specially convened meeting of the Society of Quality Assurance (SQA) representing laboratories operating under Good Laboratory Practices (GLP’s). The pros and cons to the GLP community of varying degrees of involvement with NELAC/NELAP were presented. Ms. Trovato then introduced members of ELAB and some of the concerns the group intends to address, including the GLP issue.

Mr. Longest then recognized the long-term contributions to NELAC of Al Tholen, recently retired Chief of NIST’s National Voluntary Laboratory Accreditation Program (NVLAP).

Concurrent Committee Working Sessions

For two days following the opening plenary session, concurrent working sessions involving all 11 standing and administrative committees were held. Progress made by each committee, as well as principal unresolved issues (and time frames for addressing them, if defined) are listed below. In keeping with the goals established for the Interim Meeting, all working sessions were of an open-forum format; a session typically included committee members, federal and state representatives, as well as representatives from laboratories, accrediting organizations, industry and the general public.

Accreditation Authority -- These working sessions were the first ever for the committee. As a result, many unresolved issues remain -- clear definition of “accreditation authority” and an “accreditation body;” concerns regarding loss of accreditation, international recognition of NELAC-approved accreditation authorities; and the role of third-part accreditors as accreditation bodies. All sections of the NELAC draft standards dealing with accreditation authority will be presented by the committee for review at the next NELAC annual meeting.

Accreditation Process -- Principal concerns covered a wide range of topics -- clarification as to whether federal government laboratories are to be included within the scope of NELAP; the appropriate frequency for announced and unannounced on-site assessments; the need for a more detailed definition of

“environmental laboratory,” especially as it relates to remote sites and mobile facilities; the appropriate frequency for proficiency testing and appropriate number of PT samples; consistent specification of the retention time for laboratory records; and better definition of “key laboratory personnel.” Issues related to a national database, such as the nature of the information to be included, its administration, and its availability in times of government shut-down, were discussed at great length. The standards will be amended as written comments and input from other committees are received.

Conference Management -- A major issue concerned the need for establishing regular schedules for annual and interim meetings. Concern was raised that the tentative mid-summer date for the Second Annual Meeting would come near the end of some states’ fiscal years. It was also suggested that annual meetings be held in different cities and that interim meetings continue to be held in Washington, DC. The State of Texas offered to host the 1997 Annual Meeting. The impact of charging a conference registration fee was discussed, as were the merits of allowing poster sessions and exhibitors at annual meetings. The committee is actively seeking up to five additional members.

Education and Outreach -- The committee initial session opened with a full demonstration of the NELAC Bulletin Board on the TTN. Concerns about benefits and limitations of the bulletin board were discussed. It was suggested that other avenues (appropriate environmental journals, notices accompanying widely distributed proficiency samples) be considered for more complete and efficient dissemination of NELAC information to interested parties. The International Laboratory Accreditation Conference (ILAC) was recommended as a model of effective inter-communication because of the level of mutual recognition among its member organizations. A contest was suggested as a means for developing a new NELAC logo.

Implementation -- Considerable information had been gathered since the February annual meeting concerning various state approaches to laboratory accreditation. A major point of discussion was the need for a model regulation that would enable NELAP-type requirements on environmental laboratories to be legislated at the state level. Work ahead for 1996 includes completion of model regulations and legislation and distribution to all states for comment or adoption.

Membership -- A critical issue for this committee was determination of the best tools (accurate, timely, interactive and with e-mail capability) for communication to and among NELAC members. The Technology Transfer Network (TTN) seems to be well-suited, especially if input from EPA Regional Offices and “all points bulletins” from NELAC could be incorporated. The committee also wants to contact federal agencies and states without designated House of Representatives delegates. The committee seeks to work closely with the Education and Outreach Committee to present a consistent message accentuating the benefits of NELAC and to develop educational and communications tools.

On-Site Assessment -- Review of the draft standards regarding on-site assessments revealed many issues as needing clarification or definition, either by members of this committee or in conjunction with other committees. Unresolved issues included the extent to which assessors should be responsible for reporting health and safety concerns and violations of the law; development of assessor training requirements, assessor training program standards, on-site checklists, and an assessor manual; grandfathering of assessors with other assessor certifications; better definition of “conflict of interest” and codes of conduct for assessors; the frequency of on-sites assessments and the appropriateness of announced and unannounced assessments. It is the intention of the committee to seek input from other committees on many of these issues early in 1996, to establish draft training requirements and training program standards by April 1996 and to develop checklists and the assessor manual as the NELAC standards themselves evolve.

Proficiency Testing -- The focus of this committee quickly moved to issues regarding providers of proficiency test (PT) samples. Because it is likely that multiple providers will be required as opposed to a single national provider, great concern was raised about lack of consistency that might arise in PT samples. It was recommended that detailed qualifications be developed for potential PT providers, and that all selected providers be placed under very stringent QA/QC oversight. Other issues addressed included proper use of blind PT samples, frequency of proficiency testing, use of multiple testing periods, PT sample concentrations, and PT sample stability. Mixed support was given to having all PT results data handled as part of a national database and not in individual state databases. Non-supporters questioned data confidentiality, results turn-around time, and affordability. The committee hopes to develop criteria for both PT's and PT providers by May 1996.

Program Policy and Structure -- The work of this committee involved detailed review and editing of the NELAC Constitution and By-Laws. Most articles of both documents will be revised by February 1996 and be ready at that point for approval vote. Review of Chapter 1 of the draft standards by the committee and review of the Constitution and By-Laws by legal staff of EPA, as well as revision of a limited number of sections within articles of the By-Laws, remain to be completed by May 1996.

Quality Systems -- As a result of its thorough editing the Quality Systems section of the NELAC draft standards, the committee sees the need to develop more consistency between the standards and its own definitions section. It was also recommended that more ISO 25 and ISO 9000 language be incorporated where appropriate. Suggestions were made to resolve concerns of some attendees who feared that small laboratories may not be able to provide a technical director and/or quality assurance officer. Committee work will continue through April 1996 on developing protocols for establishing method detection limits, adding text to the draft standards regarding quality control measures, data review/validation, disposition of records for out-of-business laboratories, physical facilities, and laboratory support equipment.

Standards Coordination -- Revisions made to the NELAC draft standards by a particular committee will no doubt have implications on sections of the standards being handled by other committees. Many committees are awaiting input from other committees before they can complete revision of the sections for which they are responsible. The intent of this committee is to provide consistency, avoid duplication, identify gaps, and resolve conflicts as the NELAC standards are prepared for presentation at the next Annual Meeting. Members are eagerly being sought.

Closing Plenary Session

The closing plenary session of the NELAC Interim Meeting was convened by Chair Robert Stephens. Dr. Stephens' comments included: observations on the enthusiastic participation of the various committee members and meeting attendees alike in discussing and resolving the technical issues; a summary of NELAC achievements to date; and a reminder of the challenges that lie ahead.

Each committee chair then presented a brief activity report for his or her group. These committee summary reports included the highlights of discussions in the committee sessions, an itemization of unresolved issues, future plans, and timetables for completion of those plans. A need was expressed by several chairs for their committee to coordinate its respective activities with that of other committees dealing with similar issues so that uniform actions could be taken. Each chairperson has designated an individual to serve as a liaison with the Standards Coordination Committee.

The closing plenary session ended with comments from Ms. Jeanne Mourrain, NELAC Executive Secretary, who outlined the next steps. Work should continue in earnest on the revisions to the NELAC

draft standards, and the revised standards will be placed on the bulletin board when completed. The results of the 1995 Interim Meeting will be reported to the EMMC Policy Council and will likewise be published on the TTN. A meeting of the EMMC Ad Hoc Panel will be convened and a meeting with other Federal agencies will be scheduled, including reporting to the Interagency Steering Committee on Standards. The ELAB Federal Advisory Committee will meet via teleconference and an ELAB Subcommittee on GLP's will be formed.